

PATENT COOPERATION TREATY

REC'D 07 NOV 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:
CHARLES E. DADSWELL
GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY DEPT.
FIVE MOORE DRIVE, PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **03 NOV 2005**

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

PR60714WO

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US05/03479

28 January 2005 (28.01.2005)

30 January 2004 (30.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C07D 213/56, 231/12, 239/42; A61K 31/415, 416, 4418, 505 and US CL: 544/329, 332; 546/340; 548/309.7, 375.1; 514/275, 357, 405, 406

Applicant

SMITHKLINE BEECHAM CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

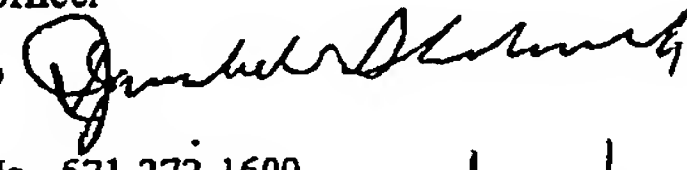
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Date of completion of this opinion
29 September 2005 (29.09.2005)

Authorized officer

Deepak Rao 
Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/03479

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/03479

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
☒ claims Nos. 4,6-8 and 10-14

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4,6-8 and 10-14 are so unclear that no meaningful opinion could be formed (*specify*):

the claims are improper multiple dependent claims under PCT Rule 6.4(a)

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

- ☐ no international search report has been established for said claims Nos. _____

- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/03479

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-3, 5, 9</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-3, 5, 9</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-3, 5, 9</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 5 and 9 meet the criteria of novelty and inventive step set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the instantly claimed compounds and/or methods of use of the compounds, see US 5,863,924.

Claims 1-3, 5 and 9 meet the criteria set out in PCT Article 33(4), because the compounds are disclosed to be useful as pharmaceutical agents, and thus meet the criteria of industrial applicability because the subject matter claimed can be made or used in industry.

PATENT COOPERATION TREATY

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From the
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To:
CHARLES E. DADSWELL
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 03 NOV 2005		
Applicant's or agent's file reference PR60714WO		
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US05/03479	International filing date (day/month/year) 28 January 2005 (28.01.2005)	Priority date (day/month/year) 30 January 2004 (30.01.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): C07D 213/56, 231/12, 239/42; A61K 31/415, 416, 4418, 505 and US CL: 544/329, 332; 546/340; 548/309.7, 375.1; 514/275, 357, 405, 406		
Applicant SMITHKLINE BEECHAM CORPORATION		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

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For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Date of completion of this opinion 29 September 2005 (29.09.2005)	Authorized officer Deepak Rao Telephone No. 571-272-1600
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/03479

Box No. I Basis of this opinion

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2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/03479

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
☒ claims Nos. 4,6-8 and 10-14

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4,6-8 and 10-14 are so unclear that no meaningful opinion could be formed (*specify*):

the claims are improper multiple dependent claims under PCT Rule 6.4(a)

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

- ☐ no international search report has been established for said claims Nos. _____

- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

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- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/03470

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-3, 5, 9</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-3, 5, 9</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-3, 5, 9</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 5 and 9 meet the criteria of novelty and inventive step set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the instantly claimed compounds and/or methods of use of the compounds, see US 5,863,924.

Claims 1-3, 5 and 9 meet the criteria set out in PCT Article 33(4), because the compounds are disclosed to be useful as pharmaceutical agents, and thus meet the criteria of industrial applicability because the subject matter claimed can be made or used in industry.